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February 24, 2006

BY ELECTRONIC FILING

The Honorable Kent A. Jordan
United States District Court
844 North King Street
Wilmington, DE 19801

Re: *Biovail v. Andrx Pharmaceuticals LLC et al.*,
Civil Action Nos. 05-586 (KAJ)

Dear Judge Jordan:

Plaintiff Biovail respectfully requests that the Court compel Defendant Andrx to supplement its responses to Biovail Interrogatory Nos. 1 and 2, and to produce documents regarding the proposed sale, and development of its generic copies of Biovail's Cardizem LA. These issues are scheduled to be addressed at the February 28, 2006 discovery conference.

I. Andrx's Responses To Interrogatory Nos. 1 and 2 Are Deficient

Andrx's responses to Interrogatory Nos. 1 and 2 are deficient, even at the present stage of the litigation. Interrogatory Nos. 1 and 2 seek the factual and legal bases for Andrx's contentions that the '791 patent is not infringed and invalid, respectively. (See Exh. A, Andrx responses to Interrogatory Nos. 1 and 2). Andrx's responses state that the '791 patent is invalid as anticipated and/or rendered obvious in view of EPO 0 320 097 ("EPO 097"). However, those responses fail to provide any explanation how EPO 097 anticipates the '791 patent, or would have rendered it obvious. Andrx's responses simply provide a conclusory allegation that the claims of the '791 patent would read on EPO 097. (See Exh. A).

Anticipation requires a particular showing that each and every element of a claim is set forth in a single prior art reference. See *Kegal Co. v. AMF Bowling, Inc.*, 127 F.3d 1420, 1429 (Fed. Cir. 1997). Obviousness requires a showing of: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claims and the prior art; and (4) why the differences between the claims and the prior art would have been obvious. See *Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339, 1343 (Fed. Cir. 2000). Andrx's responses provide none of the requisite information needed to support a defense of anticipation or obviousness. As a result, Biovail has no idea how Andrx came to the conclusion that EPO 097 is an invalidating reference, and has no basis upon which to prepare a rebuttal to Andrx's invalidity defense.

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Despite several letters requesting that Andrx supplement these interrogatory responses, Andrx maintains that during the January 26, 2006 discovery conference the Court reviewed its interrogatory responses, and made a determination that they were “sufficient for this stage of the case.” (*See* Exh. B, Andrx’s February 17, 2006 letter at 3). The Court’s instructions, however, were clear. Your Honor instructed *both* parties to be “forthcoming,” and to “give responsive discovery to the properly propounded contention interrogatories” (*See* Exh. C, Tr. 12-13). While Biovail is in compliance with the Court’s instructions, and will serve supplemental responses on February 27, 2006, Andrx has completely ignored the Court’s clear instruction that it likewise supplement its own responses.

II. Andrx’s Refusal To Produce Documents

Andrx refuses to produce documents regarding the proposed sale, and development of its generic copies of Biovail’s Cardizem LA.

Biovail’s Document Request Nos. 12, 16, 18, 36, 42, 46-47, and 66 seek, among other things, documents regarding Andrx’s projected sales, projected market share, marketing plans, and business plans regarding anticipated marketing, sale, and licensing of its proposed tableted products. (*See* Exh. D, Andrx responses). The documents are plainly relevant to the issue of commercial success, which is a secondary consideration of nonobviousness. Indeed, Andrx seeks the same type of sales and marketing information from Biovail. Nevertheless, Andrx has not provided any reason for its refusal to produce the requested documents.

Biovail’s Document Request Nos. 58-60 seek, among other things, documents regarding the ingredients used in the various drug formulations that Andrx tried during development of its proposed generic tableted products, including purchase orders and raw material receipts. (*See* Exh. D). Andrx has refused to produce its purchase orders and raw materials receipts apparently on the basis that the only relevant documents regarding ingredients are those that are included in its ANDA. (*See* Exh. B, p. 4). Biovail is entitled to know how Andrx developed its proposed tableted products. Without Andrx’s purchase orders and raw material receipts, Biovail is unable to determine the composition of each drug formulation that Andrx tried during development. By example, Andrx’s laboratory notebooks include many experiments employing the use of various ingredients. The laboratory notebooks identify each ingredient by reference to an Andrx receiving number found on Andrx’s raw material receipts. They, however, do not always include information identifying the grade of the ingredient. Without this information it is impossible to determine what was used in the experiments.

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For the reasons above, Biovail respectfully requests that the Court compel Andrx to supplement its responses to Biovail Interrogatory Nos. 1 and 2, and to produce the requested documents.

Respectfully,

/s/ Jack B. Blumenfeld (#1014)
Jack B. Blumenfeld

/cbn
Attachment

cc: Peter T. Dalleo, Clerk (By Hand w/Attachment)
Richard L. Horwitz, Esquire (By Hand and E-Mail w/Attachment)
Steven A. Maddox, Esquire (By E-Mail w/Attachment)
Joseph M. O'Malley, Jr., Esquire (By E-Mail w/Attachment)